

EXHIBIT 155

DEPARTMENT OF HEALTH & HUMAN SERVICES
Administration

Health Care Financing

Region VIII
Federal Building
1961 Stout Street
Denver, CO 80294-3538

July 25, 1996

HI-08.01.30

Grant Steffen, M.D.
Blue Cross Blue Shield of North Dakota
Medicare Part B of Colorado
600 Grant Street, Suite 600
Denver, Colorado 80203

Dear Dr. Steffen:

This is regarding a letter you released on July 11, 1996 to all the physicians who wrote in about Lupron. Your letter was in response to the many letters you received concerning the Medicare B News bulletin article on payment for Zoladex and Lupron.

As you know, Medicare regulations (42 CFR 405.517) provide for payment for drugs based on the lower of charges, the Estimated Acquisition Cost (EAC) or the median of the national Average Wholesale Price (AWP). Through your letter, it has been brought to our attention that you have been requesting invoices from physicians to price the drugs Zoladex and Lupron applying what you believe to be the EAC criteria. On August 12, 1994, our Regional Information Letter (RIL) 94-435 instructed you to immediately suspend any data collection efforts through surveying the physicians until we could obtain the required approval from the Office of Management and Budget (OMB). No further instructions have been released since then. We believe that your letter soliciting invoices from these physicians is essentially a survey and would require OMB approval. Therefore, we request that you send out another letter to the same physicians who received your letter dated July 11, 1996 and retract your request for invoices.

Next, you have advised us that, prior to your letter of July 11, 1996, you had received an invoice for Zoladex quite by accident. Our policy is if you receive an invoice associated with a particular claim, you have the discretion to price that particular claim based on the invoice. However, one invoice does not meet the requirements of establishing an EAC. Therefore, at this time, there should be no drugs paid based on EAC. Effective immediately, you should revise your pricing for Zoladex to allow the AWP. Additionally, if you do receive any invoices as a result of your letter, you may not use them to price these drugs. We recommend that you do not automatically go back and adjust any claims for Zoladex, however, if you receive specific requests for adjustments, you should honor them.



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During your telephone conversation with Jill Merrill of my staff you had asked what the policies are when the Food and Drug Administration (FDA) approves a new drug and no AWP is available to price the claim. In this circumstance, we recommend that you hold the claim until an AWP can be determined. You also asked if you could request an invoice if you believe that the AWP was extremely inflated. Under no circumstances should you be requesting invoices to determine pricing for drugs.

When you are determining pricing for drugs, you may consider costs for inventory, waste and spoilage only when establishing the EAC. Amounts in addition to the AWP are not allowed. When determining the median of the AWP, only generic drugs should be used to establish the median unless a brand name drug is priced lower than the median of the generic drugs in which case you may include the brand name drug in the array of generics to determine the median. For example, if there are a number of brand name drugs and only one generic drug, use the one generic drug for pricing unless one or more of the brand name drugs is priced lower than the generic, in which case the lower prices are included in the array for determining the median AWP.

Dr Steffen, we appreciate your efforts to protect the integrity of the Medicare trust fund and commend the spirit of your initiative. Unfortunately, we cannot move forward on implementing EAC at this time. However, we would appreciate receiving any data you may have which demonstrates the inequity between the AWP and acquisition costs.

If you have any questions regarding this matter, you should contact Penny Finnegan or Jill Merrill of my staff at 844-4024, extension 302 or 328, respectively.

Sincerely,

Darlene Debus
Manager
Colorado State Team

cc: Jay Swope, OGC, Denver
bcc: Penny Finnegan
Bernadette Schumaker